UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVO NORDISK A/S,	:	**MEMORANDUM & ORDER**
Plaintiff,	:	06 Civ 5819 (LBS)
v.	:	
PFIZER INC.,	:	
Defendant.	:	

SAND, J.,

On August 1, 2006 plaintiff, Novo Nordisk A/S (Novo), filed a claim for patent infringement against defendant Pfizer Inc, alleging that Pfizer's new diabetes drug Exubera infringes on five patents held by Novo. Novo also filed a motion for a preliminary injunction seeking to enjoin Pfizer from making, using, selling, offering to sell, and/or importing Exubera into the United States. The motion for a preliminary injunction focuses solely on Pfizer's alleged infringement of one of the five patents at issue in the complaint, U.S. Patent No. 5,884,620 (the "'620 patent"). For the reasons set forth below, the motion for a preliminary injunction is denied.

JURISDICTION AND FACTUAL BACKGROUND

Novo's claim for patent infringement is brought pursuant to 35 U.S.C. §§ 271 and 281. The Court possesses subject matter jurisdiction over these claims pursuant to 28 U.S.C. §§1331 and 1338. Novo is a pharmaceutical company engaged primarily in selling diabetes products. Novo is a corporation organized and existing under the laws of

the Kingdom of Denmark with its principal place of business in Bagsvaerd, Denmark. (Compl. ¶ 6.) Pfizer is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in the Southern District of New York. (Id. ¶ 7.)

The '620 patent was issued to Aradigm Corporation on March 23, 1999, for an invention entitled "Inhaled Insulin Dosage Control Delivery Enhanced by Controlling Total Inhaled Volume." (Compl. ¶ 9.) Novo has acquired all rights, title, and interest to the '620 patent. (Compl. ¶ 28.)

Diabetes, a disease characterized by persistently high blood glucose levels, affects approximately 21 million Americans, with 1.5 million new diagnoses a year. (Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 7.) Approximately one-third of diabetics treat their disease through careful regulation of their glucose level by taking insulin. (Id.) Traditionally, insulin is administered by injection or other invasive procedures at least once per day to those diabetics who require insulin. (Id.) Many diabetics are averse to the use of needles for insulin administration, which leads to non-compliance with prescribed treatment or health damaging delay in seeking insulin therapy. (Id. at 8.) Due to this aversion, many pharmaceutical companies have been researching alternatives to the injection of insulin. (Id.)

Research has found that insulin can be introduced into the bloodstream if it is delivered into the lungs of a patient.[1] (Id. at 8.) Insulin dosing must be precise; extremes in blood sugar levels which could result from ingestion of inappropriate quantities of insulin can lead to loss of consciousness and even death. (Id.) Consistent reproduction of insulin delivery for absorption of determined quantities of insulin into the bloodstream

[1] The extent to which this research qualifies as prior art for the '620 patent is the subject of dispute.

has proven to be the biggest hurdle in perfecting an inhalable insulin product. (Id.) Novo's patents at issue purport to solve the problems encountered with previous attempts to create a breathable insulin system. The '620 patent, in conjunction with the other four patents at issue in the complaint, proposes a system for the efficient and reproducible inhalation of aerosolized insulin through the lungs and into the bloodstream to manage the blood sugar levels of diabetics. Id. Claim 1 of the '620 patent registers a

> [M]ethod of administering insulin to a human patient by inhalation and comprises:
>
> (a) exhaling a determined volume of air;
> (b) aerosolizing an insulin formulation;
> (c) inhaling the aerosolized formulation with a determined volume of air; and
> (d) repeating (a), (b), and (c) a plurality of times wherein the determined volume of air exhaled in (a) is substantially the same for each step (a) and the determined volume of air in (c) is substantially the same for each step (c).

(Id. at 9-10.) Novo argues that before the '620 patent, no one knew that repetition of a breathing technique would lead to consistent insulin dispersal in the bloodstream via the lungs, and that Exubera is dependant on their patented method. (Prelim. Inj. Hr'g Tr. 7, Dec. 4, 2006.) Novo is currently in the process of creating its own inhalable insulin system in conjunction with the '620 patent, called AERx, which is currently in clinical trials. (Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 10.) AERx's arrival on the market is estimated to occur in 2011. (Prelim. Inj. Hr'g Tr. 26.)

On December 27, 2004, Pfizer submitted to the Food and Drug Administration ("FDA") a New Drug Application ("NDA") for Exubera. (Compl. ¶ 14.) The NDA provides for the use of Exubera in the treatment of adult diabetes and hyperglycemia. (Compl. ¶ 15.) On January 27, 2006 the FDA approved the NDA. (Compl. ¶ 16.)

Exubera is the first FDA-approved device to administer insulin via the lungs of diabetics. (Pfizer Inc.'s Mem. in Opp'n at 1.) The FDA approved instructions for Exubera are:

> [(i)] Push the "blue button" on the Exubera device and "watch the insulin cloud fill the chamber";
> [ii] Breathe out normally;
> [iii] In one breath, slowly and deeply breathe the insulin cloud in through your mouth;
> [iv] Breathe out normally

(Id. at 7.) Pfizer originally intended to sell Exubera in the United States beginning in September 2006, (Compl. ¶ 17), but has delayed the launch of the drug until March 2007. (Prelim. Inj. Hr'g Tr. 60.) Novo asserts these instructions infringe on the method of breathing covered by the '620. Novo's position is that the words "breathe out normally" in the above instruction infringes on its patented method of assuring uniform predetermined quantities of inhalable insulin. (See Prelim. Inj. Hr'g Tr. 41) ("[I]f you breathe in normally and breathe out normally, that's a determined volume of air. So Pfizer's instruction is exhaling a determined volume of air because we know where the exhale started from; it started from the end of normal inhalation.")

STANDARD FOR A PRELIMINARY INJUNCTION

Under 35 U.S.C. § 283, this Court may grant an injunction to a patentee alleging infringement. As with non-patent cases, a preliminary injunction is a "drastic and extraordinary remedy that is not to be routinely granted." Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1324 (Fed. Cir. 2004). As the moving party, Novo is entitled to a preliminary injunction if it can show a "(1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) that the balance of hardships tips in its favor; and (4) the impact of the injunction on the public interest." Jack Guttman, Inc. v.

Kopycake Enter. Inc., 302 F.3d 1352, 1356 (Fed. Cir. 2002). The Court must evaluate and balance the above factors against each other and also weigh the form and magnitude of the relief requested in determining whether to issue a preliminary injunction. Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 977 (Fed. Cir. 1996); Hybritech, Inc. v. Abbot Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988). Though no single factor is dispositive, a preliminary injunction cannot issue if the patentee has not established the first two prongs of the analysis, i.e. likelihood of success on the merits and irreparable harm. Amazon.com v. Barnesandnoble.com, 239 F.3d 1343, 1350 (Fed. Cir. 2001).[2]

LIKELIHOOD OF SUCCES ON THE MERITS

In order to determine the likelihood of success on the merits the Court considers both patent validity and infringement. See id. ("[The patentee] must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) [the patentee] will likely prove that [the defendant] infringes the [] patent and (2) [the patentee's] infringement claim will likely withstand [defendant's] challenge[] to the validity and enforceability of the [] patent."). If the non-movant "raises a substantial question concerning either infringement or validity, i.e. asserts an infringement or invalidity defense that the patentee cannot prove lacks substantial merit" the preliminary injunction will not issue. Id. at 1350-51 (citations omitted).

Infringement is determined through a two-step process: first, the claims are construed, and second, the properly construed claims are compared to the accused infringing method. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir.

[2] Although the Court finds that Novo fails to establish the first two of the four criteria, for purposes of completeness all four criteria will be examined.

1995). The patentee must present a clear case supporting the validity of the patent in suit, which may be done through a showing that the patent has withstood previous validity challenges or has gone unchallenged by the relevant industry for a long period. Id. at 1359 (citations omitted).[3]

Novo contends that the '620 patent is entitled to a presumption of validity and furthermore satisfies a long-felt need for an alternative method of insulin delivery. (See Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 16-17.) Novo alleges the '620 patent is infringed by Exubera because Exubera's instructions for use, which tell the user to "breathe normally," requires the user to breathe in a "determined volume of air" which the '620 patent calls for. (See Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 19.) Novo's definition of a "determined volume of air" is that one knows "the point from which the exhalation started, [and one] know[s] the point from where the exhalation ends." (Prelim. Inj. Hr'g Tr. 24.) Novo has conceded that if Exubera's instructions did not direct the user to "breathe out normally" at the outset of the insulin treatment session, Exubera would not infringe on the '620 patent's mandate to use a determined volume of air during the breathing method. (Prelim. Inj. Hr'g Tr. 40.)

To buttress its construction, Novo presents the deposition testimony of Dr. Ronald Crystal who compared the claims of the '620 patent to the infringing method. Dr. Crystal concludes that Pfizer's instructions for Exubera's use, which tell a patient to breathe out normally, inhale deeply, and breathe out normally again, "instructs or will instruct its

[3] The '620 patent has never been the subject of litigation, but it has also gone unchallenged since the Patent and Trademark Office granted it on March 23, 1999. The fact that the '620 patent has not been challenged is not surprising since neither Novo nor any other company has attempted to market an inhalable insulin product prior to Exubera.

users of Exubera to inhale insulin using the Exubera device in the manner claimed by claim 1 of the '620 [patent]." (Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 19.)

Pfizer argues that it raises a "substantial question" concerning either infringement or validity and that Novo has not proved Pfizer's defenses lack "substantial merit." (See Pfizer Inc.'s Mem. in Opp'n at 10.) Pfizer contends that Exubera does not infringe upon the '620 patent because the patent does not cover Exubera's breathing instructions and, in the alternative, if the '620 patent does cover Exubera it is invalid because it is anticipated by the prior art.[4] (Id.)

At the outset Pfizer takes issues with Novo's definition of "determined volume of air." Pfizer argues that under Novo's construction, anytime a patient is instructed to inhale and exhale in a certain manner, this results in the patient inhaling or exhaling a determined volume inhalation. (Id.). Pfizer argues that such a construction of the '620 patent would embrace prior art breathing techniques such as the sort used for the treatment of asthma. (Id.)

Pfizer also argues that if Novo's definition of "determined volume of air" covers Exubera, then the '620 patent is anticipated by prior art in the field of inhalable insulin and is obvious to those with an ordinary level of skill in the field. Pfizer cites the "Laube JAMA" study (published in 1993) which it believes "expressly discloses each and every element of claim 1 of the '620 patent, as interpreted by Novo." (Id. at 18.) Dr. Joseph Brain, Pfizer's expert, states that construing the '620 patent's use of "determined volume of air" in the manner proffered by Novo results in the Laube study serving as prior art for the '620 patent. (Id. at 18-19.) Novo disagrees, arguing that the Laube article does not disclose exhaling a determined volume of air or disclose that repetition of inhalation and

[4] Novo does not allege that the Exubera inhaler mechanism itself infringes any of Novo's patents.

exhalation of determined volume of air is the key obtaining consistent results. (Prelim. Inj. Hr'g Tr. 45.)

The Court finds that the parties' competing interpretations of the construction of the '620 patent as well as the voluminous testimony related to contested methods of prior art raises substantial questions as to the alleged infringement by Pfizer, and the validity of the '620 patent, one which will be best served through closer inspection at trial. The Court next considers the three remaining prongs of the preliminary injunction standard.

IRREPARABLE HARM

When the patentee makes a clear showing of likelihood of success on the merits, the patentee is entitled to a presumption of irreparable harm. Smith International, Inc., v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983). This is not the case here; therefore Novo is not entitled to the presumption of irreparable harm. Novo may still establish irreparable harm without the aid of the presumption by showing that it will suffer harm not compensable in monetary terms. Atlas Power Co. v. Ireco Chem., 773 F.2d 1230, 1233 (Fed. Cir. 1985). "The patent statute provides injunctive relief to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money." Hybritech, Inc., 849 F.2d at 1457. Novo must provide "[s]ome evidence and reasoned analysis" for the conclusion that monetary recompense is inadequate. Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991).

Novo argues that as a "niche player" focusing on diabetes treatment, it has developed a reputation as an innovator with quality products. (Prelim. Inj. Hr'g Tr. 63)

Novo contends that introduction of Exubera, which absent injunctive relief will be the first inhalable insulin product to reach the American public, will tarnish Novo's reputation and result in a loss of its hard fought market share. (Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 21.) Novo asserts that the marketing of Exubera prior to launch of Novo's AERx will further harm Novo's status and market position. (Id. at 23.) Pfizer argues that any future loss Novo may suffer should it release AERx is highly speculative because AERx is more than four years away from reaching the market. (Pfizer Inc.'s Mem. in Opp'n at 36.) Assuming that AERx does eventually reach the market in 2011 other major pharmaceutical makers actively working on developing an inhalable insulin product may have preceded Novo's entry into the market. (Id. at 1.) Thus, regardless of whether or not Pfizer is enjoined, Novo's claim to preserving a role as a unique innovator in diabetes treatment will not go unchallenged.

Novo's attempts to show irreparable harm in the future for both its current market standing and for the future sales of AERx fail as, paradoxically, they are readily determinable for the purposes of monetary damages and at the same time speculative.

Should Novo prevail at trial, money damages will be readily available. Pfizer is the largest pharmaceutical company in the world, and will be providing Exubera on a prescription only basis. (Pfizer Inc.'s Mem. in Opp'n at 42.) Novo too keeps records of its prescription sales, so any drop in sales is quantifiable. (Id.) The amount of Exubera users will be easy to track, and any decline in Novo's sales due to the alleged infringement will be readily ascertainable. As the Court has noted, Novo's alleged reputation as an innovator in diabetes treatment will not be preserved by obtaining a preliminary injunction. It is uncontested that other pharmaceutical companies are further

along in developing a marketable inhalable insulin product than Novo; even assuming Novo successfully enjoins Exubera its status as an innovator will be harmed.

Novo proceeds under the assumption that it will suffer a drop in sales during interim between now and a trial on the merits. Pfizer states that it is currently planning on marketing Exubera only to diabetics suffering from a form of diabetes, those with Type 2 diabetes "uncontrolled by 2 oral agents"[5] for which Novo currently does not offer treatment. (Id. at 8-9.) Thus Pfizer asserts that its present intent is to reach a market entirely different than that which Novo now reaches or seeks to reach. While it is possible that Pfizer could expand the scope of its intended users going forward, or that doctors would prescribe Exubera on their own for other types of diabetics during the interim prior to a trial on the merits, Novo's market share will not be affected by Exubera. As stated above, AERx is years away from its launch date; at that time, other companies may have taken over the field, newer products may become available, or all inhalable insulin products could fail to find acceptance in the market place.

Patents provide the right to exclude others from using one's invention and money damages are not always an adequate remedy for infringement. Hybritech, Inc., 849 F.2d at 1457. In this case, however, Novo has only shown that the future market harms it may suffer between now and trial are compensable by money damages except to the somewhat amorphous claim to a role as the premier pharmaceutical company in the treatment of diabetes, a claim that for the reasons stated above the Court does not find persuasive. The harms Novo may suffer between now and trial are compensable by money damages because of the availability of prescription records to quantify the harm,

[5] Other forms of diabetes are not treated with insulin, or are treated with other forms of insulin which Pfizer does not plan to market.

the lack of any Novo product on the market in the immediate future, and Pfizer's ability to pay a large damages award. Therefore the Court finds this prong to weigh in favor of Pfizer.

BALANCE OF HARDSHIPS

When balancing hardships the Court "must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted" Hybritech, Inc., 849 F.2d at 1457.

The Court agrees with Pfizer's view that diabetes is not a single product field; there are various courses of treatment available with various insulin therapies. (Pfizer Inc.'s Mem. in Opp'n at 44.) Ignoring the fact that the success of Exubera, or later AERx, is not guaranteed and that Pfizer does not intend to market Exubera to a class of diabetics currently served by Novo's products, Novo argues that it should not be faced with a loss of significant sales of insulin based diabetes treatments to Pfizer as many of its customers who do not accept injecting insulin will switch to the less invasive inhalable insulin option that Exubera provides. (Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 24.) Even if Pfizer's marketing plans change before trial, the balance of hardships would still favor Pfizer.

Pfizer has invested huge sums of money in this product, all of which would be unfairly frozen pending this litigation should Pfizer later show it did not infringe the patents at issue.[6] The money invested includes development costs for the product and

[6] The exact amount is under seal.

training sales persons and doctors for future prescribing of the product.[7] If Pfizer has infringed the patent, as stated above, Novo is still years away from having AERx reach the market, and will suffer no loss in revenue for AERx in this regard. Also, if Pfizer is shown to have infringed and is later enjoined, Pfizer will have already opened the market to this new type of therapy. The balance of hardships strongly favors Pfizer.

PUBLIC INTEREST

"[I]n a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief" Hybritech, Inc., 849 F.2d at 1457. Enjoining the release of a new and less invasive treatment for diabetes would quite obviously be contrary to the public interest, particularly in the interval between now and trial.

Pfizer contends that Exubera will allow diabetics who are currently not coping well with their diabetes or afraid to begin injecting insulin to try and control their disease in a new manner. There is a strong public interest favoring such a device. Novo argues in its briefs that it is against the public interest to start patients on a new diabetes treatment plan, only to later enjoin that method. However, at oral argument, Novo conceded that there was no medical risk in switching back from inhalable insulin to injectable insulin. (Prelim. Inj. Hr'g. 165.) While it may take a former Exubera user

[7] Pfizer has hired approximately 4200 pharmacists and certified diabetes educators to aid in training prospective patients. (Pl.'s Mem. in Supp. of its Mot. for Prelim. Inj. at 12-13.) Exubera has already been launched to 5,300 physicians, and, "contingent on supply, Pfizer expects to launch Exubera to an additional 10,000 [physicians] in January 2007, 10,000 more in February, and a remaining 46,000 physicians in March 2007." (Pfizer Inc.'s Mem. in Opp'n at 42.)

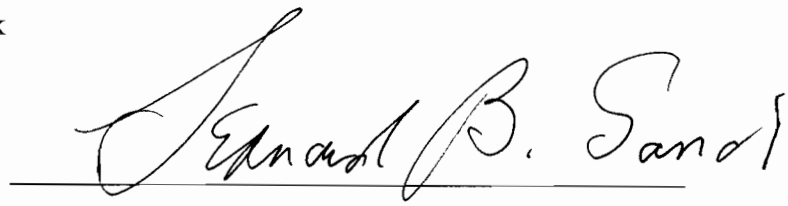
"some period" to adjust to a new method, without any medical harm this is clearly a risk worth taking in favor of the public interest. (Id.)

At oral argument, Novo proposed a preliminary injunction wherein any "patient who can't for medical reasons inject insulin or have a diagnosis of their doctor that they're needle phobic and won't inject insulin" would be allowed to use Exubera. (Id. at 174.) This proposal would of course substantially defeat Pfizer's present marketing plan.[8] It may or may not be affordable for Pfizer to produce a limited, and perhaps not cost-effective, run of a new drug for only a select few patients with serious phobia problems. Furthermore, such a preliminary order does not do much to alleviate Novo's concern that those who use Exubera and are later forced to stop after trial will be harmed, it only limits the class of those at risk to the very people who most need this new form of therapy in the first place. Therefore the Court finds that the public interest weighs in favor of a denial of the motion for a preliminary injunction.

CONCLUSION

For the reasons stated above, the Court denies the motion for a preliminary injunction. The parties are directed to submit to the Court by February 1, 2007 a proposed schedule for the future processing of this litigation.

Dated: New York, New York
December 14, 2006



U.S.D.J.

[8] See supra note 7.